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**ABSTRACT:**

A medical connector is for use in transferring fluids to and from a patient. The connector has a primary conduit, which has an upstream branch in fluid communication with a primary source of fluid and a downstream branch in fluid communication with a patient. The connector also has a secondary conduit in fluid communication with said primary conduit. Additionally, the connector has a hollow, resilient valve positioned such that the primary fluid can flow through the valve when the valve is in a decompressed state. The valve has a tab extending into the secondary conduit such that a luer inserted in the secondary conduit compresses the tab, thereby preventing flow of the primary fluid through the connector while permitting both flow of fluid to the patient from the luer and flow of fluid from the patient to the luer.

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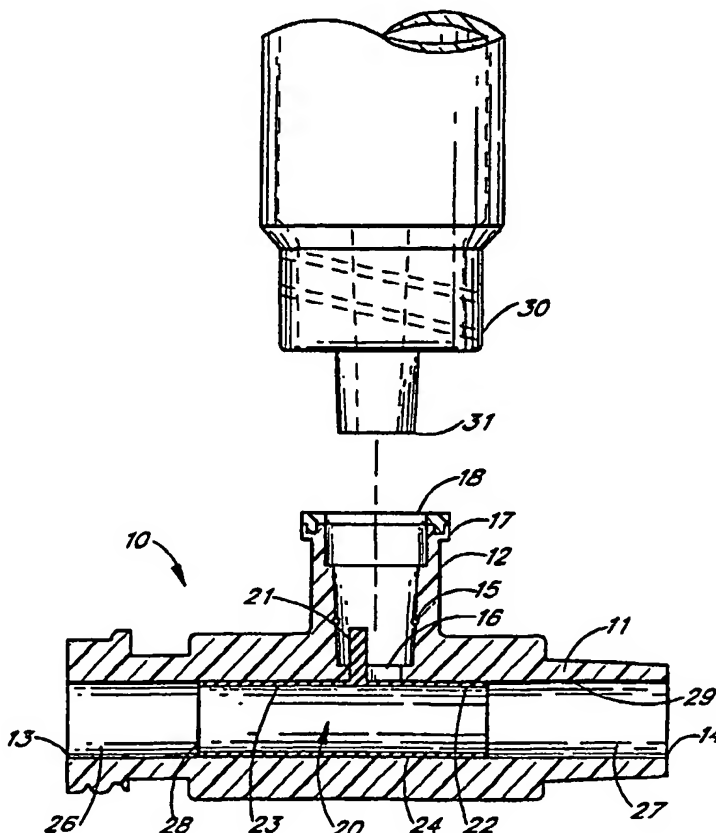


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<b>(21) International Application Number:</b> PCT/US96/09996 <b>(22) International Filing Date:</b> 7 June 1996 (07.06.96) <b>(30) Priority Data:</b> 08/480,615 7 June 1995 (07.06.95) US <b>(71) Applicant:</b> ICU MEDICAL, INC. [US/US]; 951 Calle Amanecer, San Clemente, CA 92673 (US). <b>(72) Inventor:</b> LOPEZ, George, A.; 166 Emerald Bay, Laguna Beach, CA 92651 (US). <b>(74) Agent:</b> ALTMAN, Daniel, E.; Knobbe, Martens, Olson & Bear, 620 Newport Center Drive, Newport Beach, CA 92660 (US).	<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

**(54) Title:** MEDICAL CONNECTOR**(57) Abstract**

A medical connector is for use in transferring fluids to and from a patient. The connector has a primary conduit, which has an upstream branch in fluid communication with a primary source of fluid and a downstream branch in fluid communication with a patient. The connector also has a secondary conduit in fluid communication with said primary conduit. Additionally, the connector has a hollow, resilient valve positioned such that the primary fluid can flow through the valve when the valve is in a decompressed state. The valve has a tab extending into the secondary conduit such that a luer inserted in the secondary conduit compresses the tab, thereby preventing flow of the primary fluid through the connector while permitting both flow of fluid to the patient from the luer and flow of fluid from the patient to the luer.



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**MEDICAL CONNECTOR****Background of the Invention****Field of the Invention**

5 This invention relates to the field of medical devices using a valve for transferring medication intravenously from one location to another. More specifically, this invention is directed to an improvement in medical valves to ensure that the patient receives the entire dosage of medication, while also providing a means for withdrawing blood from the patient.

**Background Discussion**

10 The manipulation of fluids for parenteral administration in hospital and medical settings routinely involves the use of connectors for facilitating the movement of fluids between two points. Oftentimes it is desirable to have the patient receive medication from a number of different sources using the same IV. Such a system may be accomplished, for example, by using a Y-connector, a piggy-back connector, a T-connector, or a manifold. Such devices have at least one secondary conduit connected with the primary conduit to add one or more secondary fluids, such as drugs, for example, to the primary fluid being infused into a patient  
15 through the primary conduit.

Many connectors or valves, especially those employing several mechanical components, have a relatively high volume of fluid space within them. A serious problem in the medical field has been the existence of this "dead space" at the intersection between the arm and the main bore in medical connectors which prevents the patient from receiving the full dosage of medication, since some of the medicine remains  
20 in the dead space of the connector. For example, in several prior art manifolds the operator inserts a syringe into the secondary conduit to introduce a secondary fluid into the primary fluid stream. However, because of the dead space that exists between the end of the syringe and the primary conduit passage, some of the secondary fluid will remain in the junction between the secondary conduit and the primary conduit.

Previous valving devices have focused on removing the undesirable dead space in such devices.

25 A one-way valving apparatus formed in a manner such that creation of undesirable volumetric dead space is substantially precluded is shown in U.S. Patent No. 4,666,429 to Stone and U.S. Patent No. 3,416,567 to Von Dardel et al. In the several embodiments described, a movable element is positioned adjacent to the inner wall of the primary conduit at the junction between the secondary and primary conduits so that the movable element forms a one-way valve. The design of the secondary conduit allows the tip of  
30 a syringe nozzle to be substantially adjacent to the movable element. The movable element is partially displaced due to fluid pressure from the flow of secondary fluid through the secondary conduit toward the primary conduit thereby allowing the secondary fluid to pass by the movable element and enter the primary conduit stream. Once the secondary fluid passes through the junction, the movable element returns to its original position, blocking the junction between the primary and secondary conduits.

35 In the intravenous environment, it is often desirable to utilize a device having the capability of both

introducing fluid medication or withdrawing blood from a patient. However, the movable element of the '429 and '567 patents provide only one-way fluid flow, since the movable element is not displaced due to fluid flow in the primary passageway, and therefore, fluid from the patient cannot be drawn into the secondary conduit. Two-way valves are advantageous for drawing a patient's blood back to determine if the IV system is properly inserted into a patient's vein to provide medication. Further, two-way valves have the additional advantage of having the capacity to withdraw blood samples from the patient.

An example of a two-way valve is shown in U.S. Patent No. 5,269,771 to Thomas, et al. A hollow plunger means is extended through the valve means within a housing to provide free fluid communication between the inlet and the outlet of the device through the central passageway of the plunger means. A syringe coupled to the inlet may then introduce fluid to the patient or, in the alternative, withdraw fluid from the patient.

A serious drawback to this prior art device is the large amount of volumetric dead space that exists not only within the central passageway of the plunger means, but also within the passageways of the housing. Thus, a large amount of the medication to be transferred to the patient remains in the dead space, thereby preventing the delivery of an exact amount of medication. The delivery of an exact amount of medication may be critical in some situations when chemotherapeutic agents are being administered or small children are being treated. An inexpensive medical connector for transferring medication from a number of different sources using the same IV wherein dead space is minimized and fluid in the secondary conduit is bidirectional would be of great benefit to the medical community.

#### Summary of the Invention

The medical connector of this invention has several features, no single one of which is solely responsible for its desirable attributes. Without limiting the scope of this invention as expressed by the claims which follow, its more prominent features will now be discussed briefly. After considering this discussion, and particularly after reading the section entitled "Detailed Description of the Drawings," one will understand how the features of this invention provide advantages which include safety, reliable and repeatable performance, simplicity of manufacture and use, eradication of dead space, and capacity for one-way or two-way fluid flow.

The present invention relates to a valve positioned at the intersection of a primary conduit and a secondary conduit of a medical connector. The valve of the present invention is a hollow, resilient tube oriented along the longitudinal axis of the primary conduit. The tube, in its resting state, blocks the fluid path to and from the secondary conduit. The primary conduit has an inlet at its upstream end and an outlet at its downstream end. The primary conduit has an upstream portion defined by the portion between the upstream end and the junction with the secondary conduit, as well as a downstream portion defined by the portion between the downstream end and the junction. Fluid passing through the primary conduit will pass through the hollow valve, but will not be able to enter the secondary conduit of the connector. Extending

from the exterior side wall of the valve and into the secondary conduit cavity is a tab that is positioned off-center within the cavity of the second conduit. The outer diameter of the valve is slightly larger than the inner diameter of the primary conduit of the connector to ensure a fluid-tight fit.

The secondary conduit may be frusto-conically shaped so as to receive a standard tapered male luer.

5 A luer inserted into the secondary conduit may be located in one of two positions. At a first position the tip of the male luer contacts and rests on an annular ring or other protrusion that is integral with or attached to the inner wall of the secondary conduit a short distance above the tab of the valve. The annular ring or protrusion may be manufactured of the same plastic or other medically inert material that the medical connector is manufactured from. Alternatively, a tab may be provided within the secondary conduit to provide the same function as the annular ring.

10 To inject fluid from the secondary conduit to the patient, the luer is inserted to the first position and fluid from a syringe or other medical device in fluid communication with the luer is introduced into the secondary conduit, whereby the resulting fluid pressure partially displaces the resilient valve, allowing fluid from the syringe to pass through the luer and beyond the tube into the primary conduit. Once the fluid from the syringe has passed into the primary conduit, the resilient valve returns to its original shape, stopping fluid communication between the primary and secondary conduits. Because the distance between the tip of the luer at the first position with respect to the valve is so small, any dead space at the junction between the secondary conduit and the primary conduit is minimized. At the first position, the medical connector and valve of the present invention perform as a fluid pressure-activated one-way valve. Moreover, while the luer is at the first position, primary fluid continues to flow through the primary conduit from the upstream end thereof to the downstream end thereof.

15 To withdraw fluid from the patient into the secondary conduit, the tip of the luer is pushed further downward and rides over the annular ring or other protrusion, making an auditory "clicking" sound. The clicking sound informs the operator that the luer is located in the second position within the secondary conduit. In the second position the edge of the luer tip engages the tab of the valve and forces the tab downward. As the tab is pushed downward into the primary conduit, the walls of the valve accordingly are biased downward and the valve collapses to close off primary fluid flow through the primary conduit upstream of the intersection of the primary and secondary conduits.

25 With the male luer in the second position, the valve is maintained in its collapsed position, providing an open passageway to withdraw fluid from the patient to the secondary conduit while effectively maintaining a seal barring fluid flow through the upstream portion of the primary conduit. Since primary fluid flow is sealed off by the collapsed valve, no clamp is required in the primary conduit to pinch off the conduit and prevent primary fluid flow during withdrawal of fluid from the patient. Furthermore, the portion of the valve upstream of the junction maintains a fluid-tight seal against the inner walls of the primary conduit. Such a configuration ensures that no primary fluid is mixed with the patient's blood as the blood is

withdrawn into the secondary conduit. Thus, the present invention provides a pressure-activated valve for injecting fluid into the patient, as well as a luer-activated valve for withdrawing fluid from the patient.

Due to the novel features of the present invention, the present invention overcomes a key problem in the prior art since it provides a one-way and two-way valve with minimal dead space while also being  
5 inexpensive to manufacture.

In an alternate embodiment, instead of employing a tab attached to the valve to compress the valve, a movable tab may be attached to the inner wall of the secondary conduit. In this embodiment the tip of the male luer contacts and biases the movable tab downward. In turn, the movable tab forces the resilient valve down to a position where the valve collapses and seals off the primary conduit from primary fluid flow  
10 while providing open fluid flow communication between the secondary conduit and the patient.

#### Brief Description of the Drawings

The preferred embodiments of this invention, illustrating its features, will now be discussed in detail. These embodiments depict the novel and nonobvious medical connector of this invention shown in the accompanying drawings, which are for illustrative purposes only. These drawings include the following  
15 figures, with like numerals indicating like parts:

Figure 1 is a partial cross-sectional view of the valve of the present invention in a closed position within a medical connector.

Figure 2 is a partial cross-sectional view of the valve of the present invention in the open position within a medical connector for injecting fluid into a patient.

Figure 3 is a partial cross-sectional view of the valve of the present invention in an open position within a medical connector for withdrawing fluid from the patient.  
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Figure 4 is a partial cross-sectional view of an alternate embodiment of the medical connector of the present invention wherein the valve is in a closed position.

Figure 5 is a partial cross-sectional view of the alternate embodiment of the present invention shown in Figure 4 wherein the valve is in an open position for withdrawing fluid from the patient.  
25

Figure 6a is a perspective view of an alternate embodiment of valve of the present invention showing the valve in a closed position.

Figure 6b is a partial cross-sectional perspective view of valve shown in Figure 6a.

Figures 7a and 7b are cross-sectional views of the alternate embodiment of the valve of the present invention shown in Figures 6a and 6b where the valve is shown in a closed position and an open position, respectively.  
30

Figures 8a and 8b are cross-sectional views of an alternate embodiment of the present invention showing the valve in a closed position and an open position, respectively.

Figures 9a and 9b are cross-sectional views of an alternate embodiment of the present invention showing the valve in a closed position and an open position, respectively.  
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Figures 10a and 10b are cross-sectional views of an alternate embodiment of the present invention showing the valve in a closed position and an open position, respectively.

Figures 11a and 11b are cross-sectional views of an alternate embodiment of the present invention showing the valve in a closed position and an open position, respectively.

5        Figures 12a and 12b are cross-sectional views of an alternate embodiment of the present invention showing the valve in a closed position and an open position, respectively.

Figures 13a and 13b are cross-sectional views of an alternate embodiment of the present invention showing the valve in a closed position and an open position, respectively.

10       Figures 14a and 14b are cross-sectional views of an alternate embodiment of the present invention showing the valve in a closed position and an open position, respectively.

#### Detailed Description of the Drawings

Figure 1 illustrates a preferred embodiment of the medical connector 10 of the present invention where the valve 20 is in the closed position. Medical connector 10 comprises a primary conduit 11 in fluid communication with a secondary conduit 12 at junction 16. The primary conduit 11 has an inlet 13 at its upstream end and an outlet 14 at its downstream end. The primary conduit 11 has an upstream portion 26 defined by the portion between the upstream end (inlet 13) and the junction 16 with the secondary conduit 12, as well as a downstream portion 27 defined by the portion between the downstream end (outlet 14) and the junction 16. Valve 20 is preferably located at junction 16. The longitudinal axis of valve 20 is in alignment with the longitudinal axis of primary conduit 11. Positioned at junction 16 of medical connector 10, valve 20 in its uncompressed state prevents any fluid flow between secondary conduit 12 and primary conduit 11. Valve 20 comprises a hollow, resilient tube 24 and tab 21, where the tube 24 is further defined by upstream wall section 23 and downstream wall section 22. Tab 21 of valve 20 extends from the side wall of valve 20 into secondary conduit 12. Valve downstream wall section 22 extends a short distance downstream in primary conduit 11 beyond junction 16, and valve upstream wall section 23 may extend comparatively a longer distance upstream past junction 16. Along the inner walls of secondary conduit 12 is annular ring 15 positioned slightly above tab 21 of valve 20. Preferably, the cavity of secondary conduit 12 tapers inwardly so that secondary conduit 12 may be adapted to fit snug with an ANSI (American National Standards Institute, Washington, D.C.) standard end of a medical implement. Typically, the implement is a syringe, luer, or any one of a wide variety of conduits used in medical applications. A luer is defined as any tube for fluid communication and may also be commonly used with a medical implement. Luers may vary in shape and can be conical, cylindrical, or any other shape known to those of skill in the art. The secondary conduit 12 is defined by a proximal end 18 and a distal end which is at junction 16. Advantageously, the proximal end 18 of secondary conduit 12 can be equipped with a locking mechanism to facilitate locking of secondary conduit 12 to a variety of medical implements or connector devices. For example, referring to Figure 1, locking ears 17 near the proximal opening 18 of secondary conduit 12 are



preferably provided, such that the secondary conduit 12 can be locked into any compatible luer-lock device known to those of skill in the art.

As configured, during operation fluid from a primary fluid source (not shown) enters inlet 13 of primary conduit 11 and flows through tube 24 of valve 20 and out outlet 14 of primary conduit 11 for transmission to the patient. The outer diameter of tube 24 is preferably slightly larger than the inner diameter of primary conduit 11. Therefore, a fluid-tight fit is ensured between the valve 20 and the inner wall 29 of the primary conduit 11 to prevent any primary fluid flowing in between the walls of tube 24 and primary conduit 11 and into secondary conduit 12. With the valve 20 in this configuration, no fluid is allowed to flow between secondary conduit 12 and primary conduit 11.

Upon injection of fluid from a medical implement 30 into secondary conduit 12, one-way valving is provided for fluid flow from the medical implement 30 into primary conduit 11 and to the patient. To inject fluid from the secondary conduit 12 to the patient, the medical implement 30 is inserted into a first position in secondary conduit 12 and fluid from a medical implement 30 is introduced into secondary conduit 12.

As shown in Figure 2, the proximal end 31 of medical implement 30 is inserted into secondary conduit 12 until proximal end 31 contacts annular ring 15. Because annular ring 15 is positioned to be a very short distance from junction 16, dead space between proximal end 31 of medical implement 30 and junction 16 is minimized. With the edges of proximal end 31 resting on annular ring 15, medical implement 30 is in a first position whereupon by injecting fluid through medical implement 30, the resulting fluid pressure partially deflects resilient tube 24 to allow the secondary fluid from medical implement 30 to pass beyond valve 20 and into primary conduit 11 and into the patient. After the secondary fluid from medical implement 30 has passed through junction 16, resilient tube 24 decompresses and returns to its original shape. The ability of tube 24 of valve 20 to compress under fluid pressure and to return to its original shape is determined by the resiliency of the material used to manufacture the valve 20. By immediately returning to its original shape upon termination of fluid pressure from the medical implement 30, valve 20 prevents any back flow of fluid from outlet 14 to secondary conduit 12. Moreover, because upstream wall section 23 is longer than downstream wall section 22, the fluid pressure introduced by medical implement 30 is not great enough to push the upstream end 28 of tube 24 to overcome its fluid-tight seal with the walls of primary conduit 11. Thus, during this procedure, primary fluid flow from inlet 13 into secondary conduit 12 is prevented. Alternatively, the valve 20 may be manufactured from a material that does not require the upstream portion 23 of the tube 24 to be longer than the downstream portion 22 of the tube 24 while still achieving the advantages of the present invention.

Figure 3 illustrates the two-way valving feature of the present invention. As shown in Figure 3, proximal end 31 of medical implement 30 biases tab 21 downward, thereby compressing and maintaining tube 24 in an open, fluid communication position. In order to withdraw a sample of fluid from the patient,

proximal end 31 of medical implement 30 is pushed over annular ring 15, thereby providing an auditory "click" sound as the medical implement 30 is set in the second position. This "click" sound is an audible signal which a user may rely upon to indicate that medical implement 30 is locked into the second position within secondary conduit 12. Alternatively, the user may be able to determine the position of the medical implement 30 in the secondary conduit 12 by touch and sight, and a audible click would be unnecessary.

The edge of proximal end 31 of medical implement 30 biases tab 21 downward into the passageway of primary conduit 11. Tab 21 of valve 20 is specifically designed to be positioned off-center within junction 16 to allow the edge of proximal end 31 to contact tab 21 when medical implement 30 is in the second position. Tab 21 can be positioned off-center towards any side of secondary conduit 12. However, in certain embodiments, it is desirable to position tab 21 closer to the downstream end of primary conduit 11.

In response to the displacement of tab 21, tube 24 collapses, as shown in Figure 3, to close off any primary fluid flow in primary conduit 11 from inlet 13. Additionally, upstream wall section 23 also is displaced into the passageway of primary conduit 11, but because upstream wall section 23 is comparatively longer than downstream wall section 22 or alternatively, the strength of the material of the tube 24 does not cause separation of the upstream wall section 23 from the inner walls 29 of primary conduit 11 upstream of the junction 16, the force from medical implement 30 is not great enough to displace the upstream end 28 of upstream wall section 23 from its fluid-tight fit against the inner walls 29 of primary conduit 11. Thus, primary fluid flowing into inlet 13 is completely blocked from entering secondary conduit 12. With an open passageway maintained between outlet 14 and secondary conduit 12 through primary conduit 11, an operator may draw a fluid sample from the patient into medical implement 30. Alternatively, the two-way valving feature allows an operator to draw back a small amount of fluid from the patient into medical implement 30 to determine whether the IV system is inserted into the patient's vein so that medication may be safely and properly transmitted to the patient.

Advantageously, a clamp is not required to pinch off primary fluid flow in primary conduit 11 when withdrawing fluid from the patient, since valve 20 collapses down to effectively seal off conduit 11 when medical implement 30 is in the secondary position in secondary conduit 12. Thus, when luer 30 is placed in the first position, valve 20 acts as a pressure-activated one-way valve for injecting fluid into a patient; and when luer 30 is placed in the second position, valve 20 acts as a two-way valve for introducing or withdrawing fluid from the patient. Due to the limited number of components, the medical connector of the present invention is inexpensive and easy to manufacture.

An alternate embodiment of the two-way valving apparatus with minimal dead space is illustrated in Figure 4. In the alternate embodiment, valve 20 is a hollow, resilient tube residing within primary conduit 11 at junction 16. As in the preferred embodiment illustrated in Figures 1-3, valve 20 comprises a tube 24 having a upstream wall section 23 and a downstream wall section 22. Instead of having a tab connected

to tube 44, a tab 25 is attached to the inner wall of conduit 12 adjacent junction 16 and beneath annular ring 15. Tab 25 serves primarily the same function as tab 21 of Figures 1-3 to maintain downstream wall section 42 of valve 40 in a deformed position so as to provide fluid communication between secondary conduit 12 and primary conduit outlet 14 when medical implement 30 is in the second position. Figure 5 illustrates medical implement 30 in the second position within secondary conduit 12. Upon riding proximal end 31 of medical implement 30 over annular ring 15 and into the second position, the edge of proximal end 31 biases tab 25 downward into the passageway of primary conduit 11 to displace valve 40 from blocking junction 16, and collapsing downstream wall section 42 to close off upstream primary fluid flow from primary conduit inlet 13. Upon withdrawal of medical implement 30 from the second position within secondary conduit 12, tab 25 returns to its natural position within secondary conduit 12, allowing resilient tube 44 of valve 40 to return to its original shape.

Alternatively, annular ring 15 may be substituted for a tab, a protrusion, a ramp, or any other structure known to those of skill in the art. Preferably, annular ring 15 is made of the same material as medical connector 10, that being a plastic or any other medically inert material.

Figures 6a and 6b show an alternate embodiment of valve 20 of the present invention that may be used in medical connector 10. Valve 20 in Figures 6a and 6b have tab 21 and tube 24 with inner blocks 61 and 62 which seal off upstream primary fluid flow when tab 21 is pressed down by medical implement 30 in the second position. Figures 7a and 7b further illustrate the functioning of the alternate embodiment of the valve 20 shown in Figures 6a and 6b. Figure 7a shows the valve 20 in the closed position, while Figure 7b shows the valve 20 in the open position.

Figures 8a and 8b show another alternate embodiment of valve 20 of the present invention that may be used in medical connector 10. Valve 20 in Figures 8a and 8b have tab 21 and tube 24 with inner blocks 81 and 82 which seal off upstream primary fluid flow when tab 21 is pressed down by medical implement 30 when medical implement 30 is in the second position. (Figure 8b).

Figures 9a and 9b show another alternate embodiment of valve 20 of the present invention that may be used in medical connector 10. Valve 20 in Figures 9a and 9b have tab 21 and tube 24 with inner blocks 81 and 82 which seal off upstream primary fluid flow when tab 21 is pressed down by medical implement 30 when medical implement 30 is in the second position. Further, tube 24 also collapses when the tab 21 is compressed. (Figure 9b).

Figures 10a and 10b show another embodiment of the present invention. Two inner blocks 81 and 82 close off primary fluid flow when the medical implement 30 is in the second position with tab 21 compressed as shown in Figure 10b.

Figures 11a and 11b show another embodiment of the valve 20 of the present invention which seals off primary fluid flow upstream when tab 21 is compressed by medical implement 30 as shown in Figure 11b.

Figures 12a and 12b show another embodiment of the valve 20 of the present invention which seals off primary fluid flow upstream when medical implement 30 compresses the tab 21 as shown in Figure 12b. Valve 20 comprises a tab 21 and a gate 90 where gate 90 seals off primary fluid flow upstream in primary conduit 11 when medical implement 30 is pushed into the second position, thereby biasing tab 21 downward and forcing gate 90 to close.

Figures 13a and 13b show another embodiment of the valve 20 of the present invention which seals off primary fluid flow upstream when medical implement 30 compresses the tab 21a or tab 21b as shown in Figure 13b.

Figures 14a and 14b show another embodiment of the valve 20 of the present invention which seals off primary fluid flow upstream when medical implement 30 compresses tab 21 as shown in Figure 14b.

#### Scope of the Invention

The above presents a description of the best mode contemplated for carrying out the present invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use this invention. This invention is, however, susceptible to modifications and alternate constructions from that discussed above which are fully equivalent. Consequently, it is not the intention to limit this invention to the particular embodiments disclosed. On the contrary, the intention is to cover all modifications and alternate constructions coming within the spirit and scope of the invention as generally expressed by the following claims, which particularly point out and distinctly claim the subject matter of the invention.

**WHAT IS CLAIMED IS:**

1. A medical connector for use in transferring fluids to and from a patient, comprising:  
a primary conduit, said primary conduit having an upstream branch in fluid communication  
with a primary source of fluid and a downstream branch in fluid communication with a patient;  
a secondary conduit in fluid communication with said primary conduit; and  
5 a hollow, resilient valve positioned such that said primary fluid can flow through said  
valve when said valve is in a decompressed state, said valve having a tab extending into said  
secondary conduit such that a luer inserted in said secondary conduit compresses said tab,  
thereby preventing flow of said primary fluid through said connector while permitting both flow  
of fluid to said patient from said luer and flow of fluid from said patient to said luer.
- 10 2. The medical connector of Claim 1, wherein said medical connector further comprises a  
protrusion positioned along an inner wall of said second conduit.
3. The medical connector of Claim 2, wherein said protrusion comprises an annular ring.
4. The medical connector of Claim 2, wherein said protrusion comprises a pair of tabs  
positioned along an inner wall of said secondary conduit.
- 15 5. The medical connector of Claim 1, wherein said valve is in fluid tight engagement with  
an inner wall of said primary conduit when said valve is in a decompressed state.
6. The medical connector of Claim 1, wherein said luer may be inserted to a first position  
within said secondary conduit such that dead space in said secondary conduit is substantially minimized.
7. The medical connector of Claim 6, wherein expelling a secondary fluid from said luer into  
20 said secondary conduit deforms said valve, permitting said secondary fluid to enter said primary conduit  
and travel to the patient.
8. The medical connector of Claim 7, wherein said valve decompresses to its original  
position after said secondary fluid has passed from said secondary conduit to said primary conduit.
9. The medical connector of Claim 1, wherein said luer may be inserted to a second position  
25 within said secondary conduit such that said luer biases said tab of said valve, collapsing said valve such  
that said primary fluid is prevented from traveling past said valve, while fluid communication is maintained  
between said luer and the patient.
10. The medical connector of Claim 2, wherein said luer causes an audible sound upon  
transversing said protrusion.
- 30 11. The medical connector of Claim 1, wherein said secondary conduit further comprises a  
locking mechanism for locking said secondary conduit to said luer.
12. A method for introducing and withdrawing fluids from a patient comprising the steps of:  
inserting a luer to a first position in a secondary conduit of a medical connector, said  
medical connector having a primary conduit, a secondary conduit and a hollow, resilient valve such

that a source of primary fluid may flow through said valve when said valve is in a decompressed state and wherein said primary source of fluid is prevented from flowing through said valve when said valve is in a compressed state;

5 forcing a second fluid contained in said luer into said secondary conduit thereby slightly deforming said valve such that both said primary and secondary fluids may travel through said medical connector to a patient simultaneously;

inserting said luer to a second position in said secondary conduit such that said primary source of fluid may not transverse said valve while fluid communication is established between said luer and the patient;

10 withdrawing fluid from said patient through said primary and secondary conduits and into said luer; and

removing said luer thereby reestablishing said flow of said primary fluid from the source thereof through said medical connector to the patient.

13. The method of Claim 12, wherein an audible sound is generated when said luer is  
15 inserted into the second position in said secondary conduit.

14. The method of Claim 12, wherein said withdrawing step is conducted after said inserting said luer to a second position step.

15. The method of Claim 12, wherein said inserting a luer to a first position is conducted before said inserting a luer to a second position step.

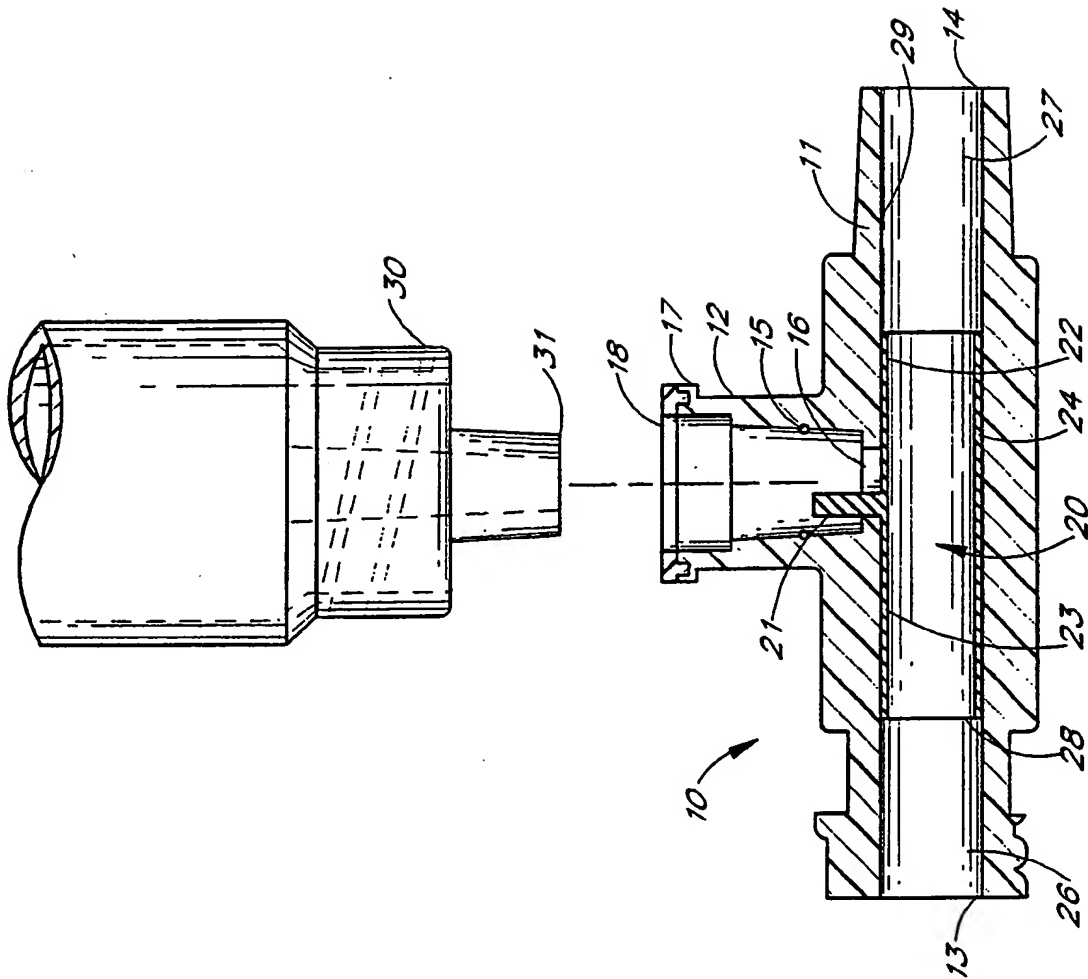
20 16. The method of Claim 12, wherein said inserting a luer to a second position is conducted before said inserting a luer to a first position step.

17. The method of Claim 12, wherein said withdrawal step is conducted before said forcing step.

25 18. The method of Claim 12, wherein said forcing step is conducted before said withdrawal step.

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FIG. 1



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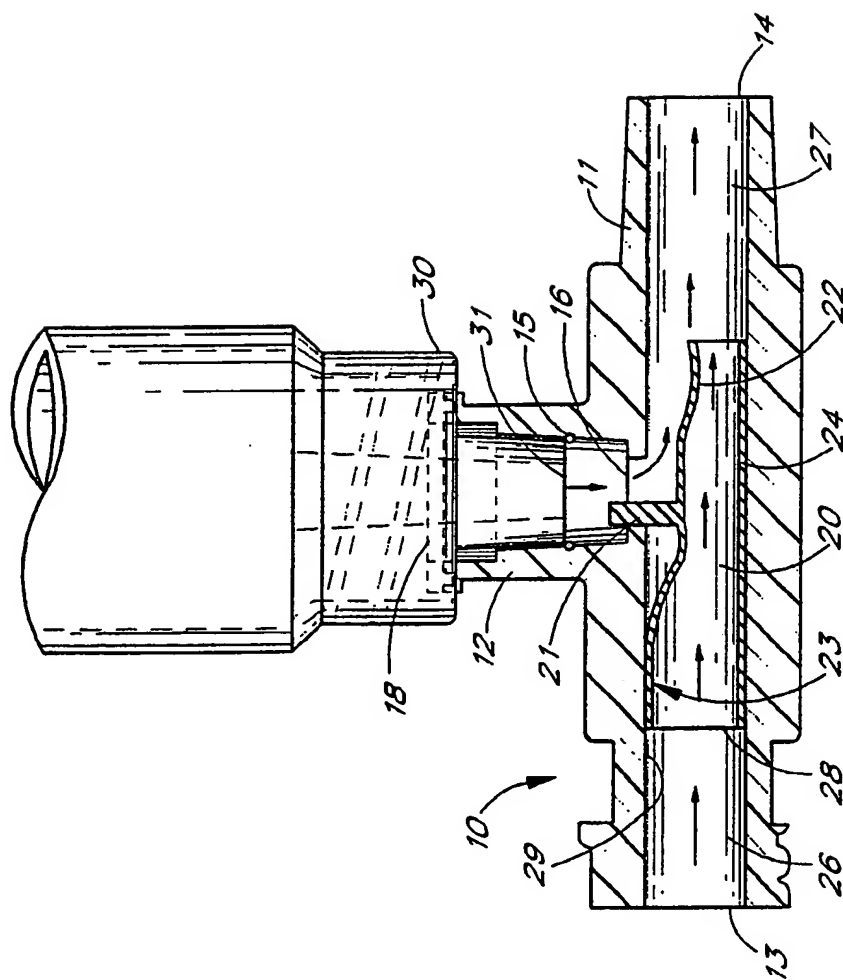


FIG. 2



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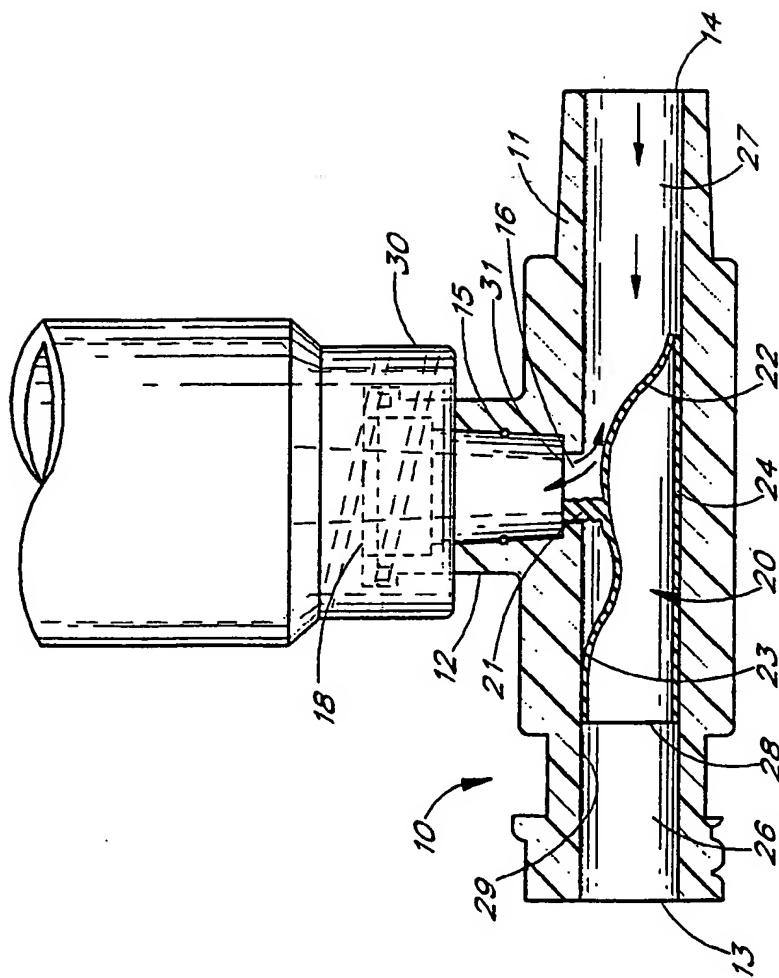
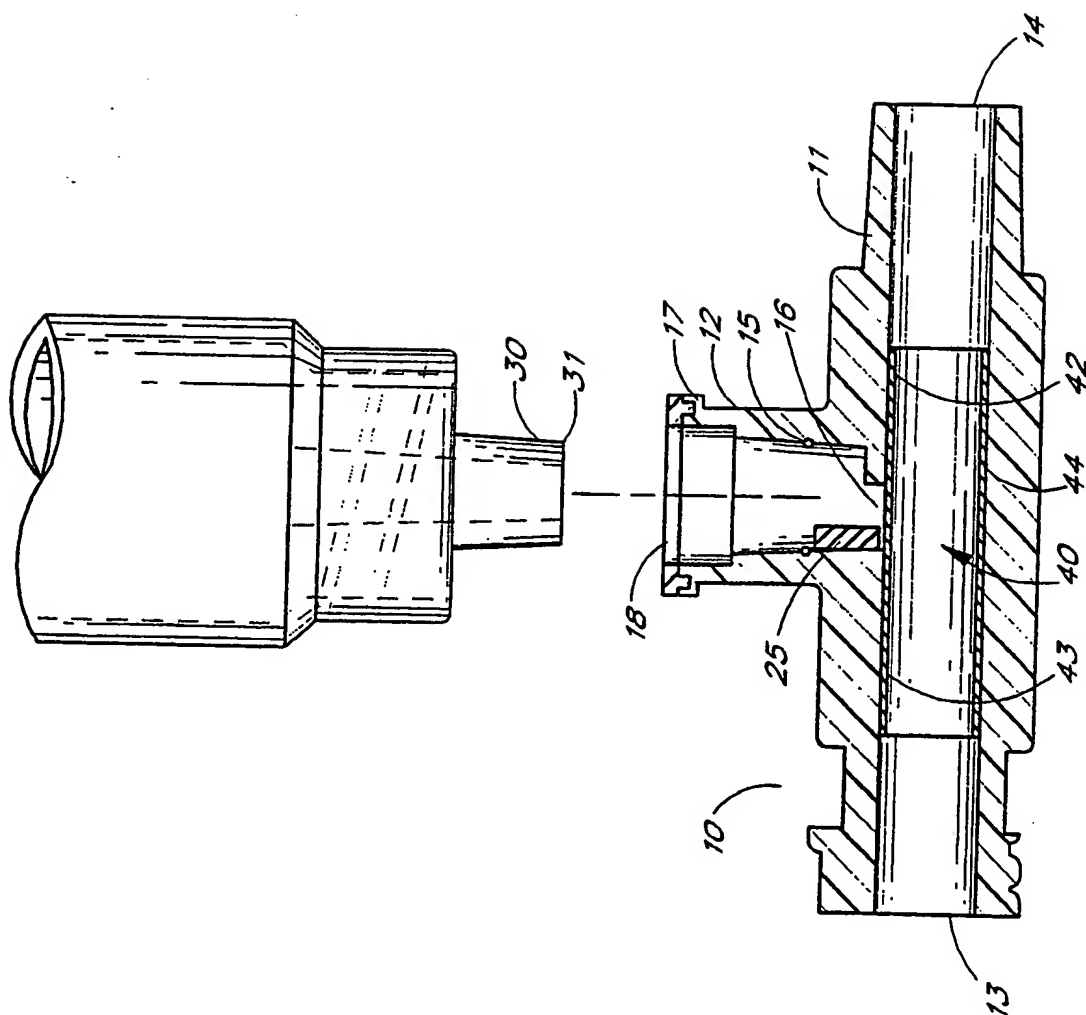


FIG. 3

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FIG. 4



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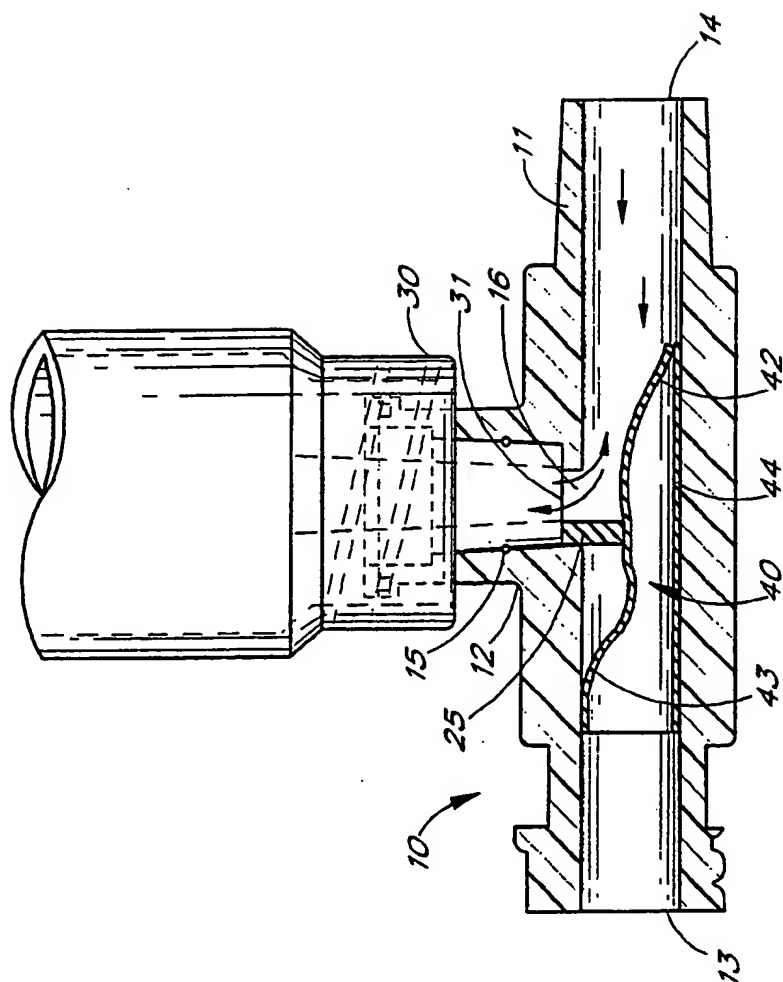
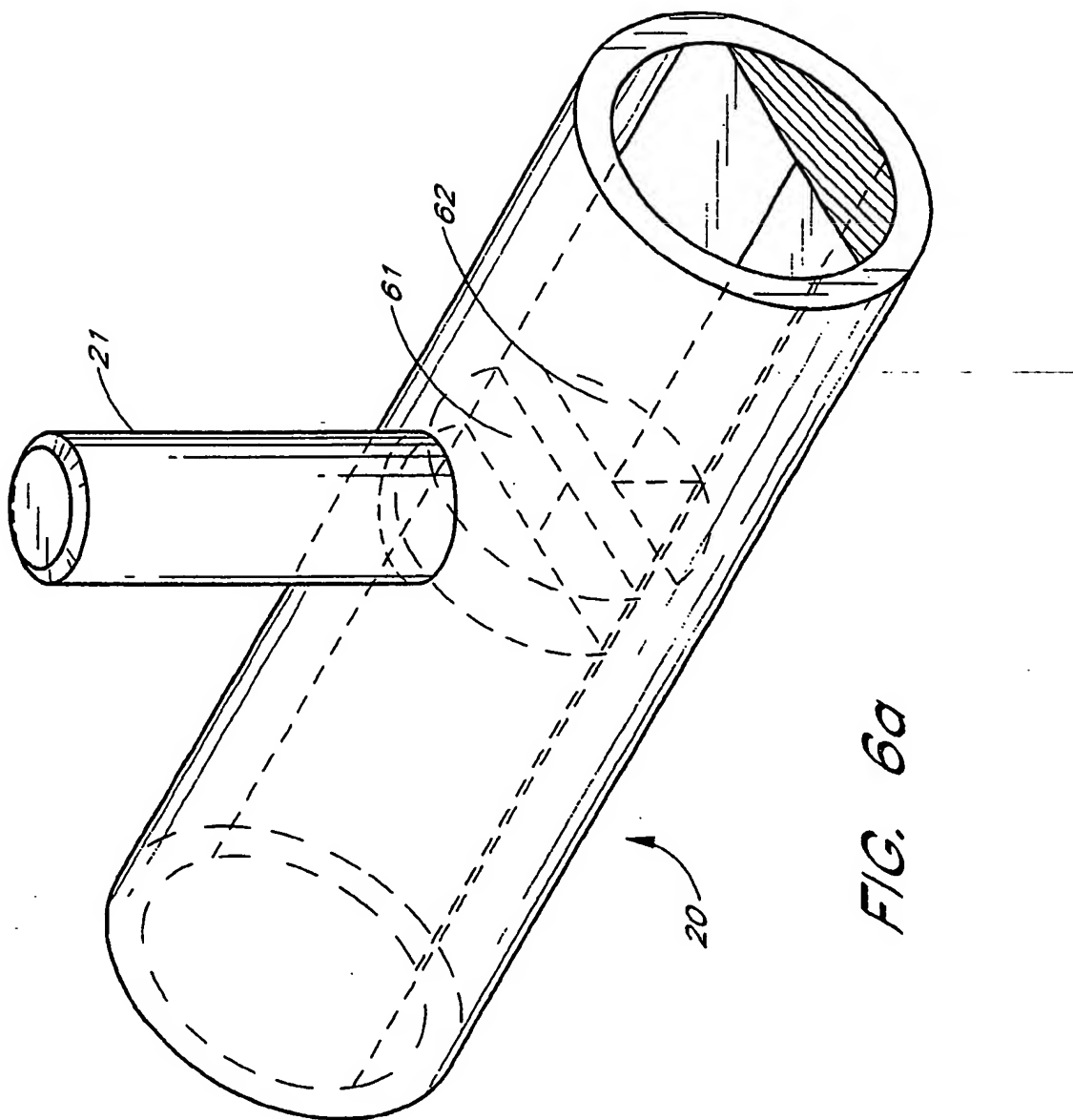


FIG. 5

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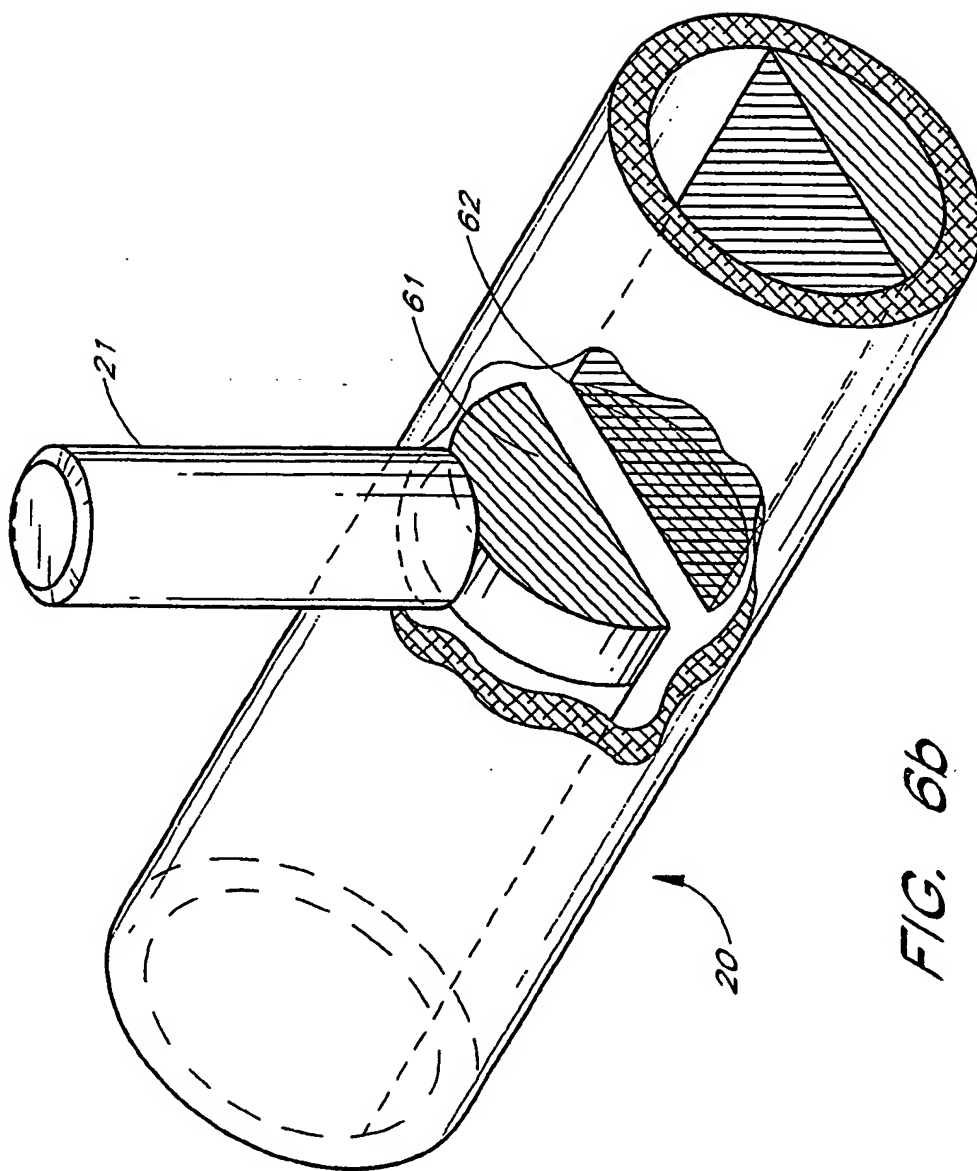
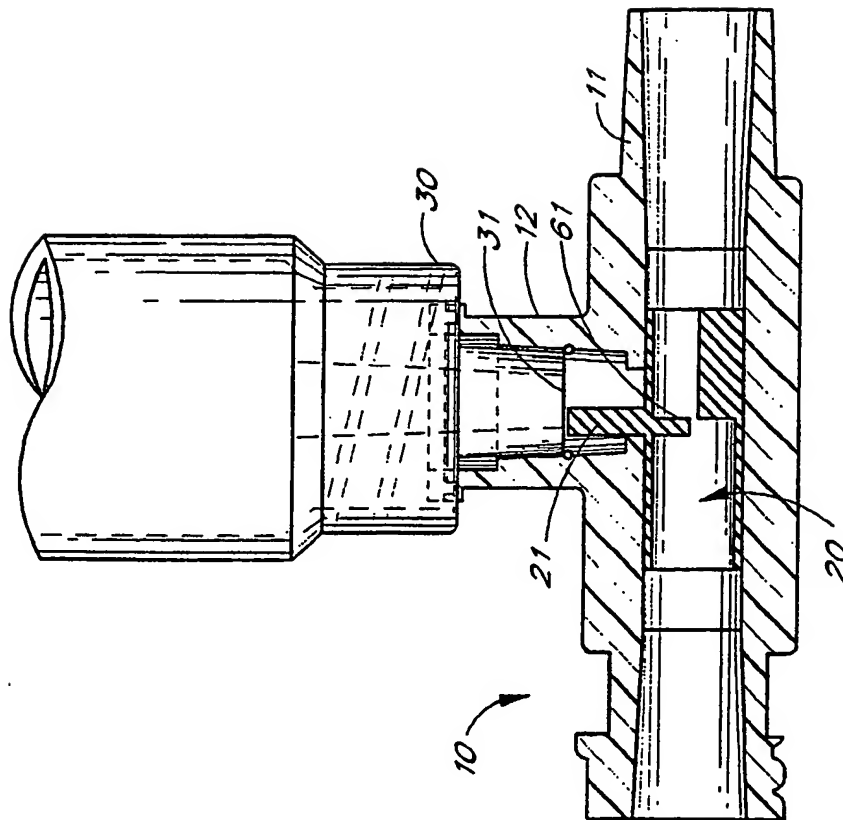


FIG. 6b

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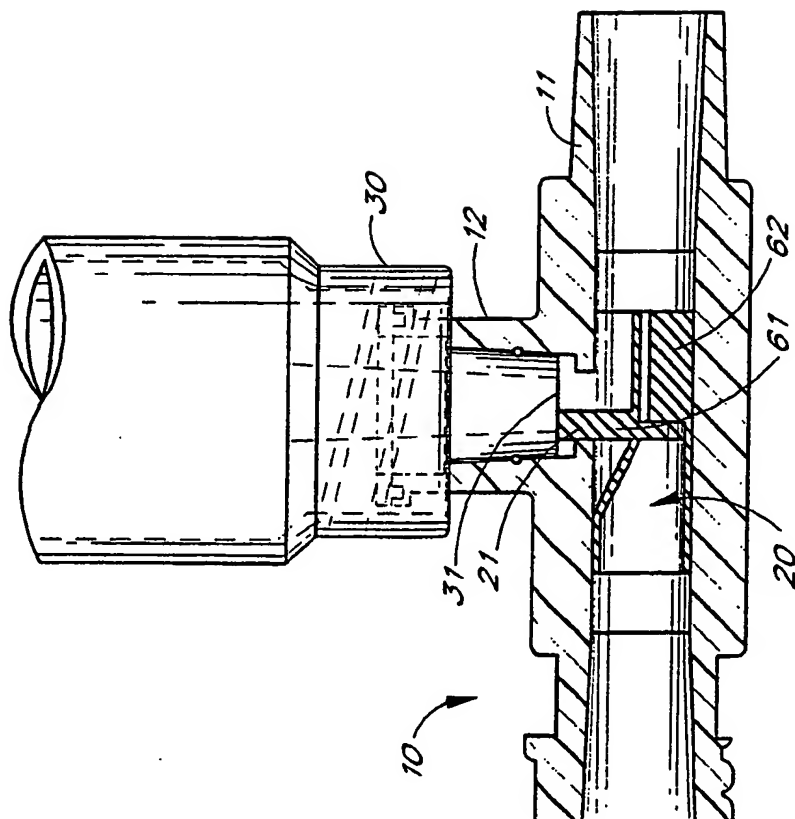
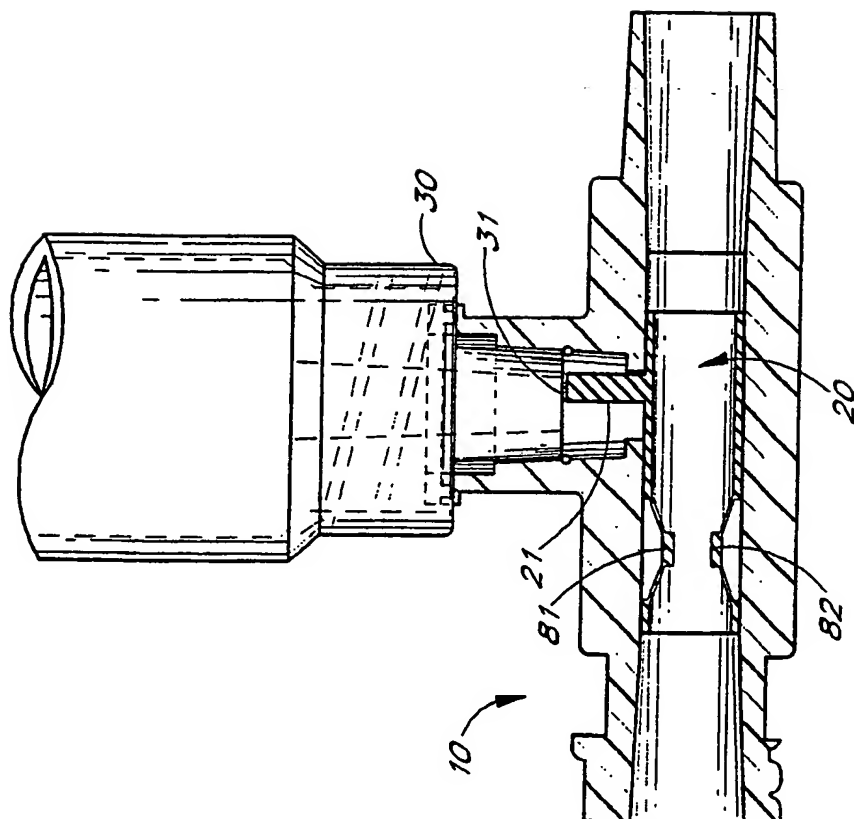


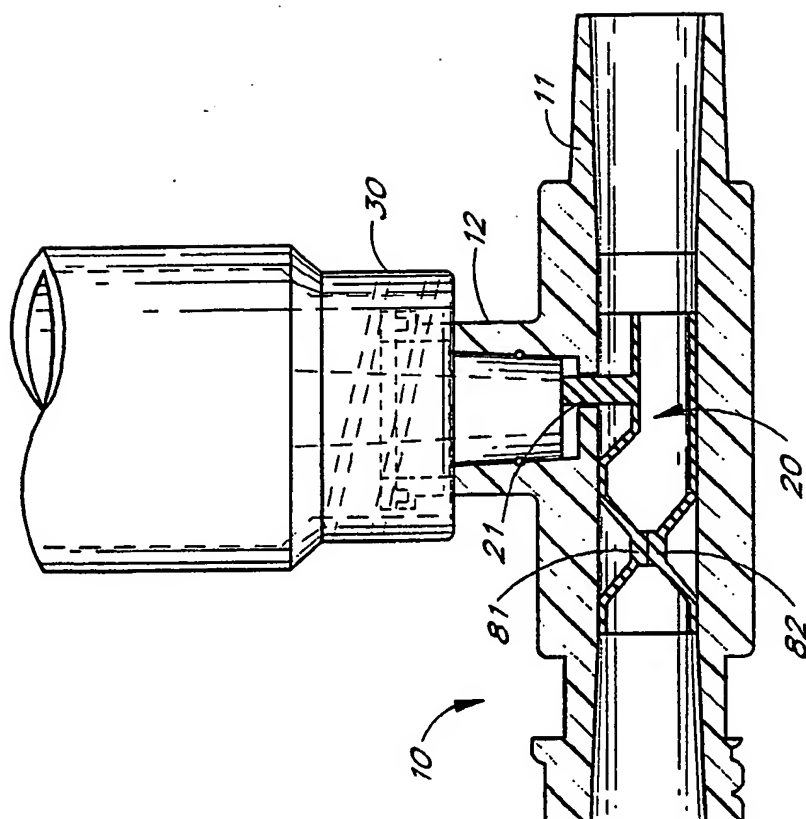
FIG. 7b

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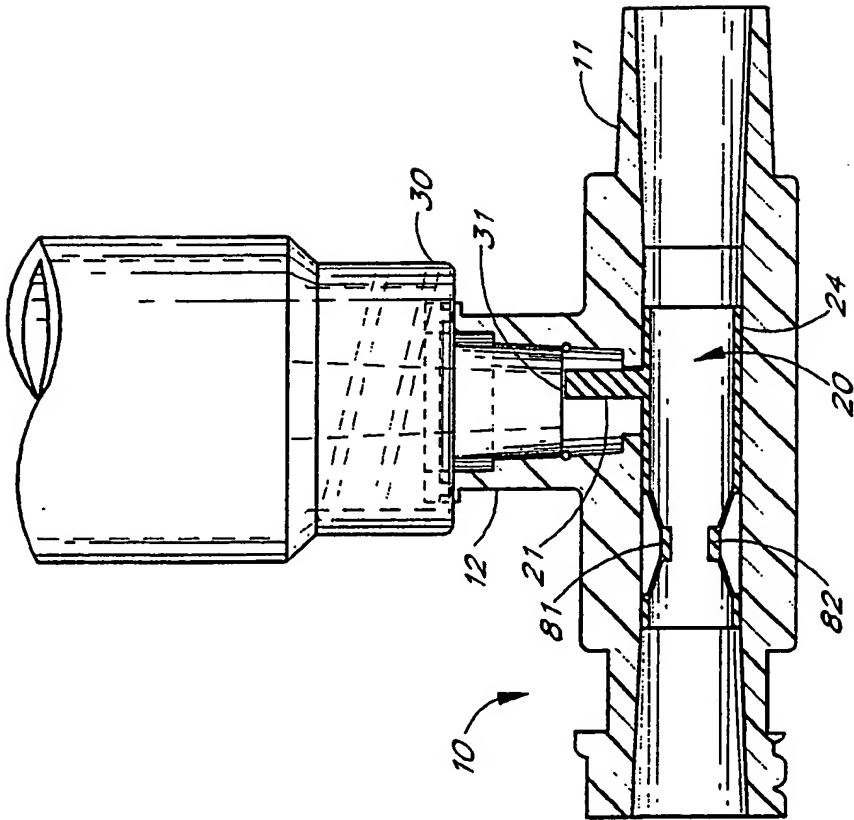


FIG. 9a

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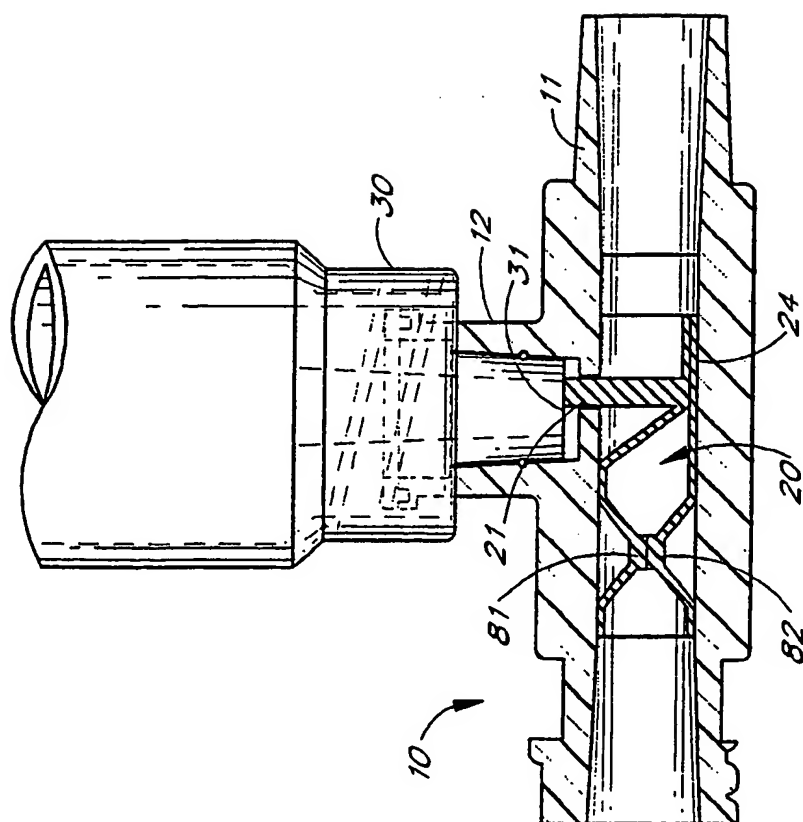
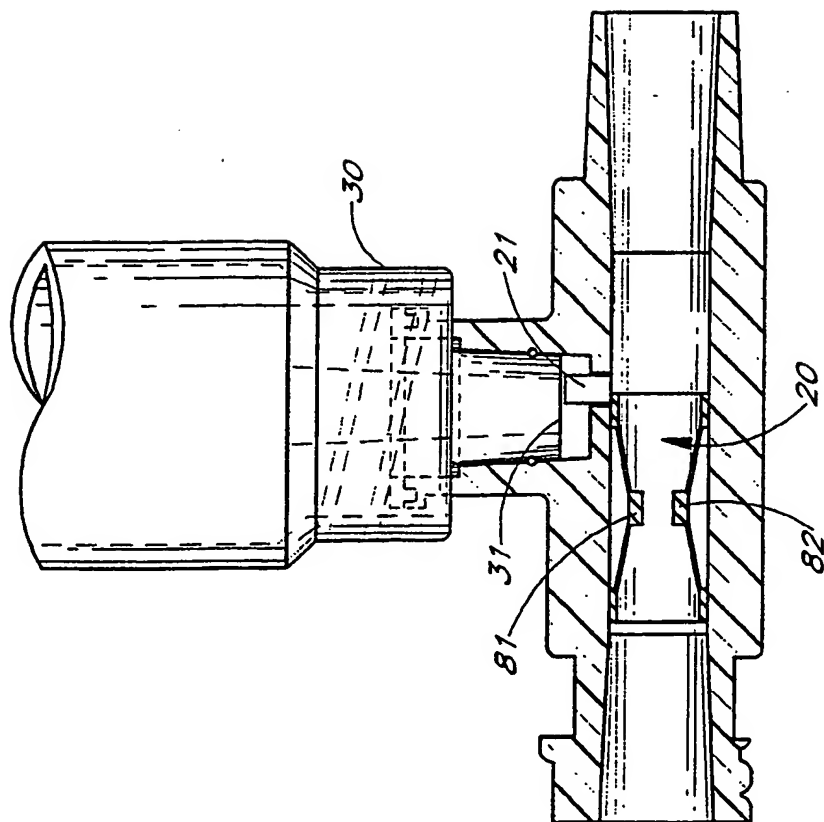
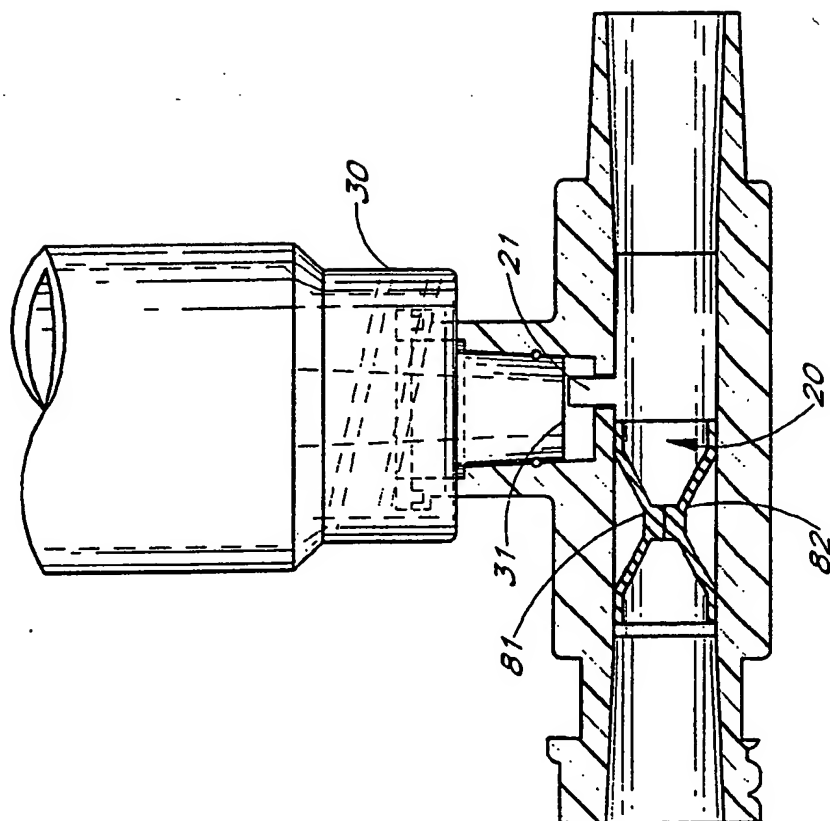


FIG. 9b

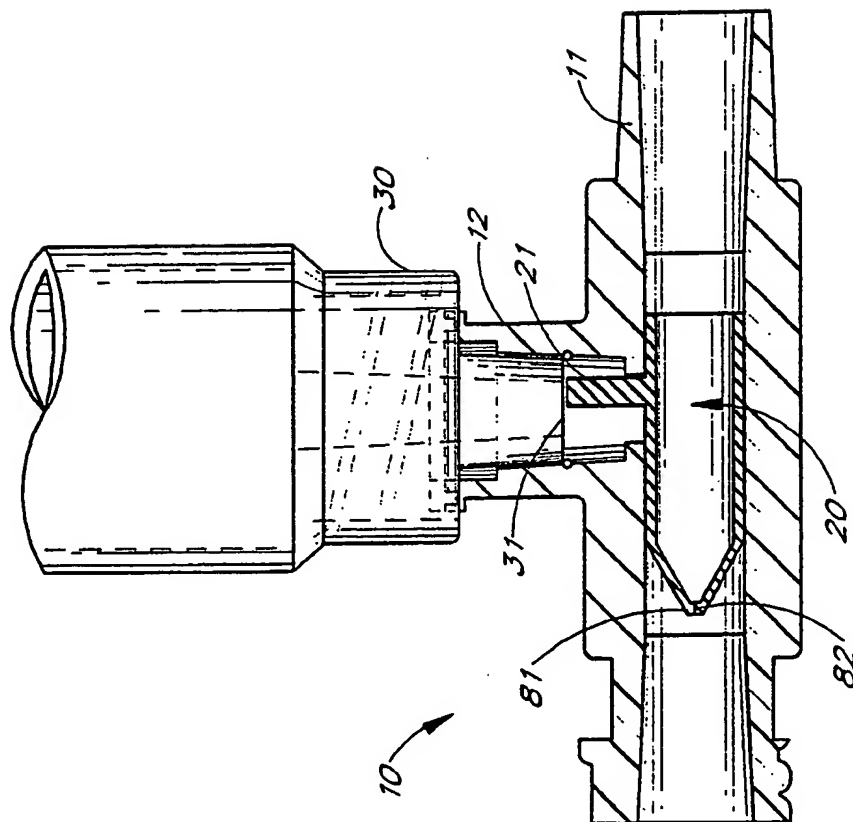
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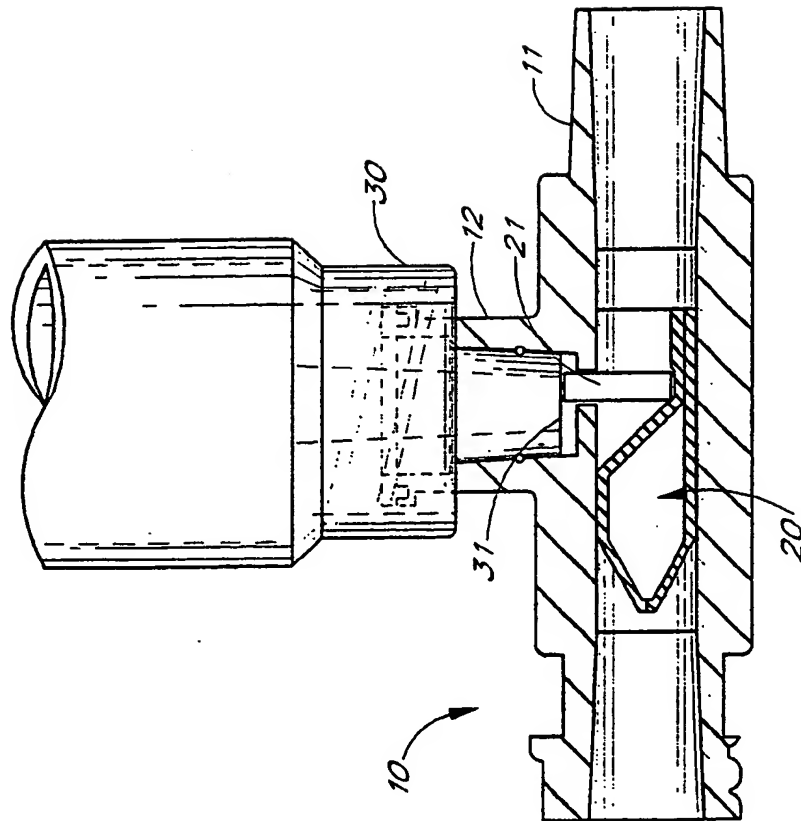


FIG. 11b

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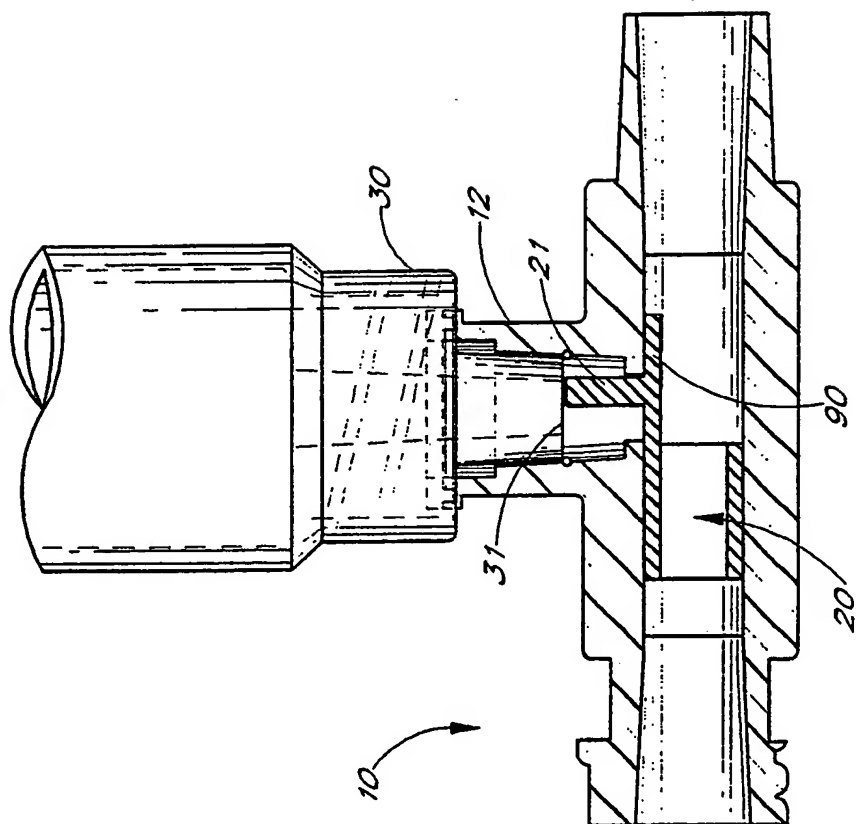


FIG. 12a



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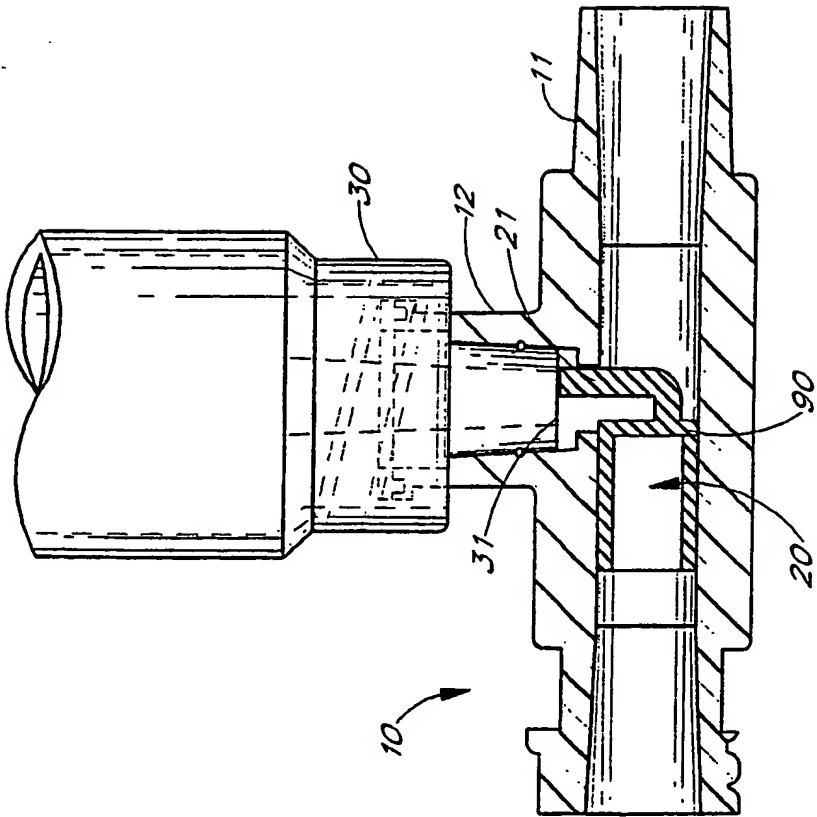


FIG. 12b

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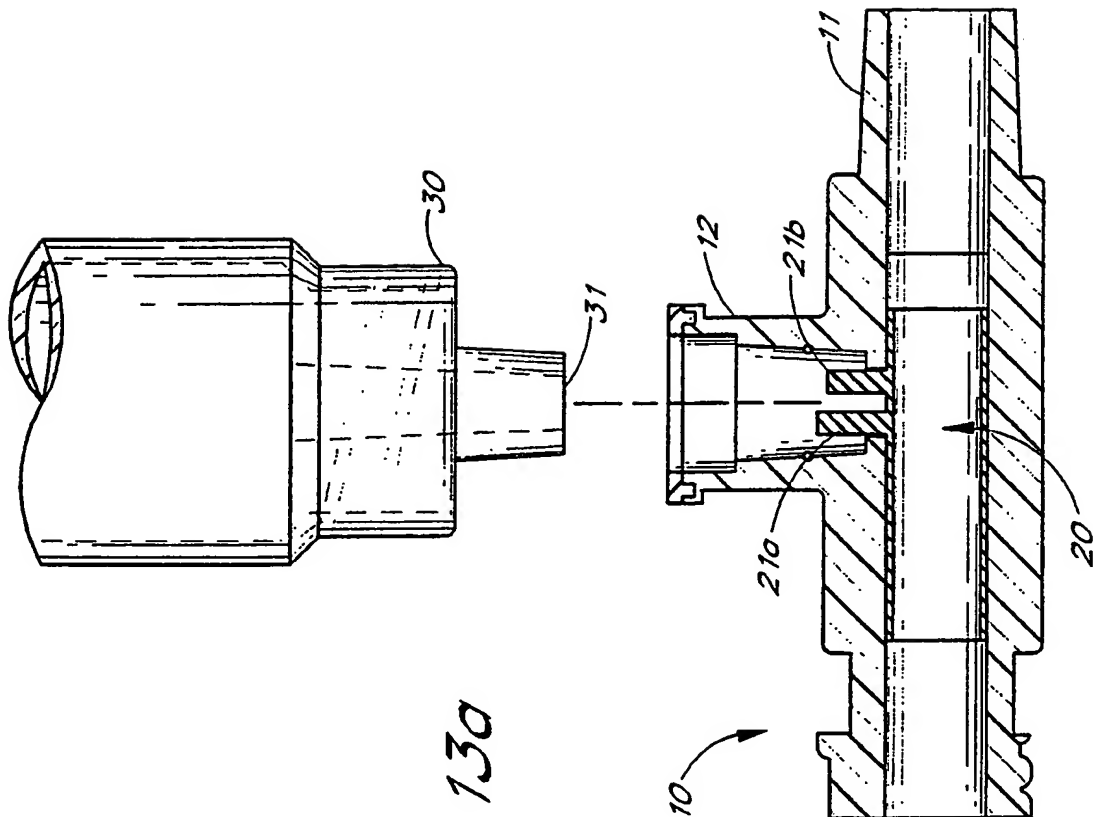
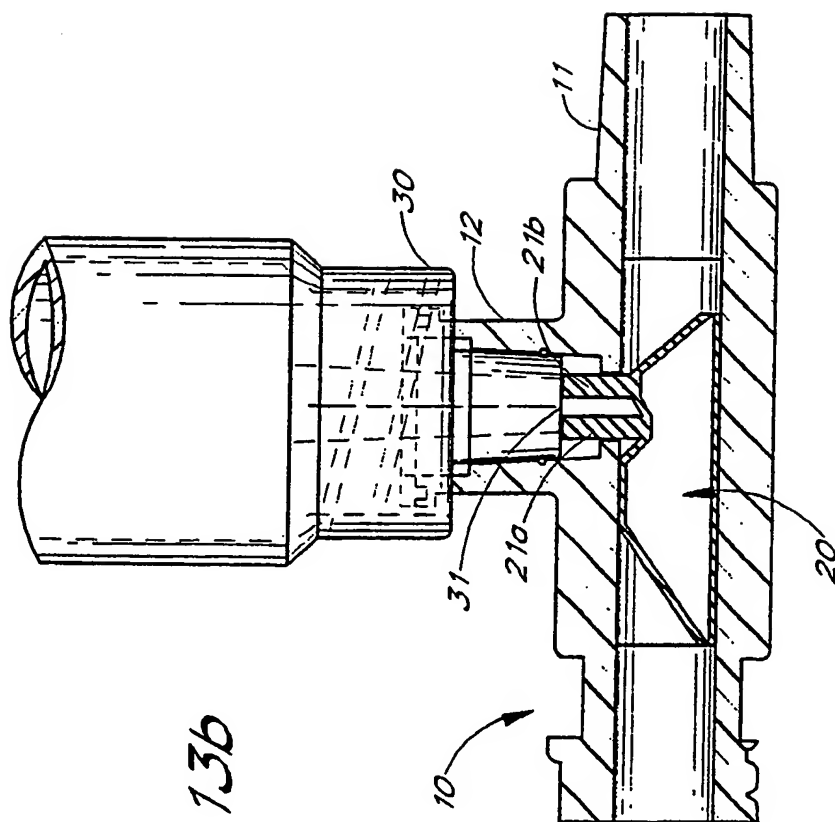
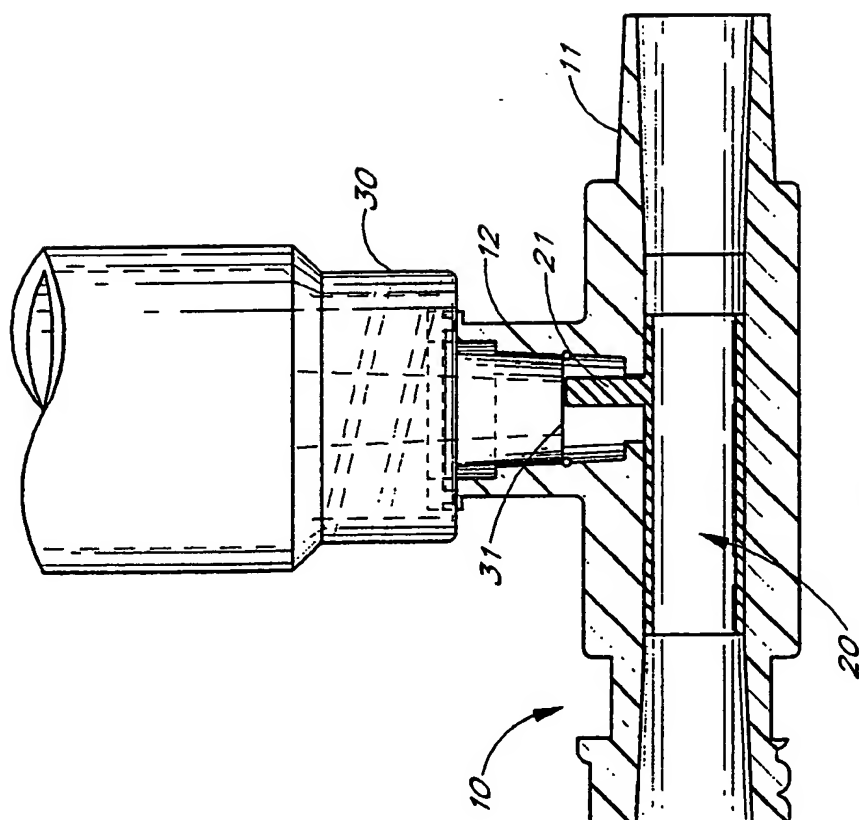


FIG. 13a

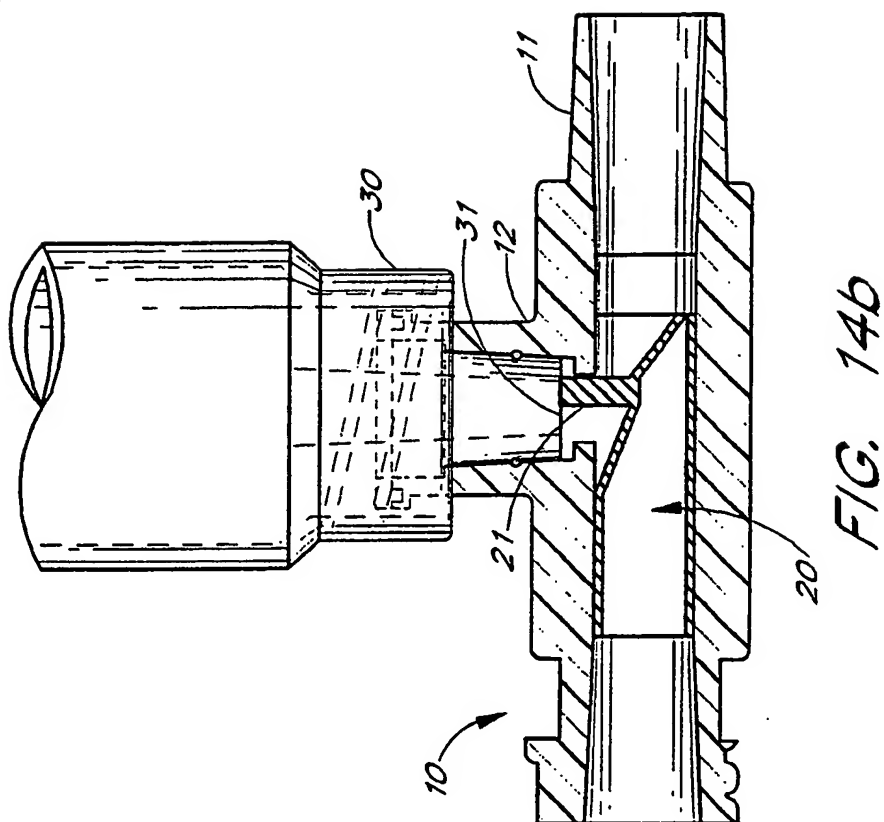
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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 96/09996

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61M39/02

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61M F16K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 240 590 (INTERMEDICAT GMBH) 14 October 1987 see column 6, line 21 - line 45 see figures 2A,2B ---	1,6,9
A	EP,A,0 370 997 (HIRNICH) 30 May 1990 see column 3, line 2 - column 4, line 45 see figures 2,3 ---	1,2,5,6, 11
A	US,A,5 098 405 (PETERSON ET AL.) 24 March 1992 see figures 2-4 -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

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Date of the actual completion of the international search

30 September 1996

Date of mailing of the international search report

11. 10. 96

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3016

Authorized officer

Schönleben, J

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 96/09996

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 12-18  
because they relate to subject matter not required to be searched by this Authority, namely:  
Please see Rule 39.1(iv) PCT.
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Int ional Application No

PCT/US 96/09996

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
EP-A-240590	14-10-87	JP-C-	1708152	11-11-92
		JP-B-	3062113	24-09-91
		JP-A-	62243563	24-10-87
		US-A-	4819684	11-04-89
-----				
EP-A-370997	30-05-90	AT-B-	391814	10-12-90
-----				
US-A-5098405	24-03-92	AT-T-	135241	15-03-96
		AU-B-	637761	03-06-93
		AU-A-	8960891	06-08-92
		CA-A,C	2057561	01-08-92
		DE-D-	69208904	18-04-96
		EP-A-	0497576	05-08-92
		ES-T-	2087443	16-07-96
		JP-A-	4303462	27-10-92
		JP-B-	6026582	13-04-94
		NZ-A-	240832	26-10-94
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